Modern Trends and Clinical Experience with Dual-Chamber ICDs: Analysis of 473 Phylax AV Implants

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Summary

The first worldwide subpectoral implantation of a dual-chamber implantable cardioverter-defibrillator (ICD) (Phylax AV, Biotronik, Germany) was performed at the Bakoulev Research Center for Cardiovascular Surgery on April 29, 1996. Currently, more than 20 % of implanted ICDs in the world are dual-chamber devices. Their development was necessitated by the clinical need for physiological (atrioventricular synchronous) pacing and for cardioversion or defibrillation of both ventricular and supraventricular tachyarrhythmia. This article provides a brief report on clinical experience with 473 Phylax AV implants in 13 European countries, including analysis of the implantation technique, the underlying indications, and the therapeutic results. Features of various dual-chamber ICD devices available on the market have been compared in view of the availability of DDD(R) pacing, sensitivity and specificity of the algorithms for detection of ventricular and supraventricular tachyarrhythmia, and options for treatment of atrial tachyarrhythmia.

Key Words

Dual-chamber ICD, discrimination between ventricular and supraventricular tachyarrhythmia, dual-chamber pacing, multi-site pacing

Introduction

Since February 1980, when Mirowski and colleagues successfully implanted the first cardiac defibrillator, the number of implantable cardioverter-defibrillators (ICDs) has increased exponentially to reach the figure of 200,000 units implanted by the year 1999 (Figure 1). The worldwide experience with 2,400 Phylax single-chamber ICDs (Biotronik, Germany), which utilized a single transvenous lead for defibrillation from the endocardial coil with the ICD housing serving as the reference point, indicated the possibility to implant the device under local anesthesia in 25 % of patients. As the simplified implantation procedure could be accomplished in about one hour, the complexity of ICD implantation approached that of routine pacemaker implantation.

Intracardiac electrogram (IEGM) monitoring in the course of ICD therapy revealed that 15 % – 40 % of patients occasionally received inappropriate shocks on supraventricular tachycardia (SVT), including sinus tachycardia, atrial flutter (Afl), and atrial fibrillation (AF). Further ICD development was therefore initiated to prevent patient discomfort and premature battery depletion associated with inappropriate shock delivery in single-chamber ICDs. Analysis of several thousands of Holter IEGMs recorded in the diagnostic data memory of the ICDs of the 3rd and 4th generation [1-8] emphasized the need for a universal dual-chamber ICD for the treatment of SVT, Afl/AF and bradycardia in addition to cardioversion/defibrillation of ventricular tachycardia (VT) and ventricular fibrillation (VF). The

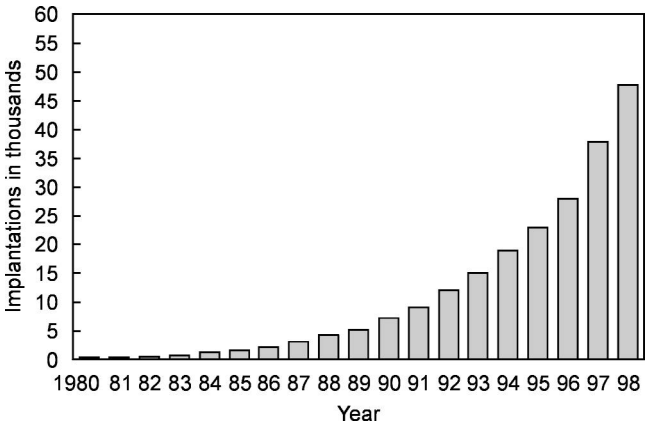
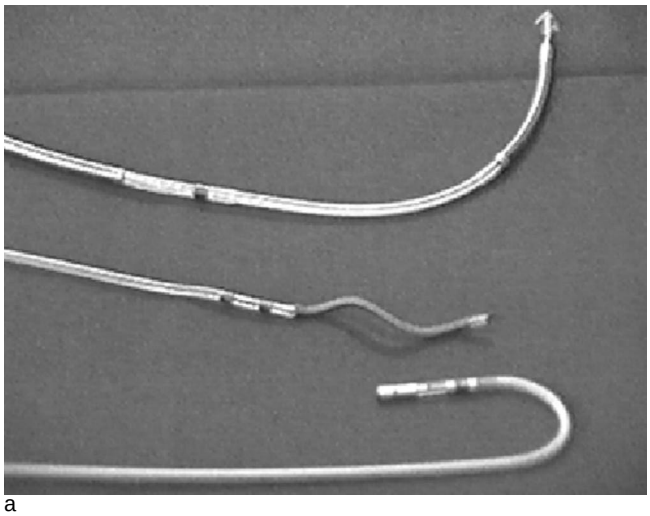


Figure 1. The number of implanted cardioverter-defibrillators (ICDs) worldwide.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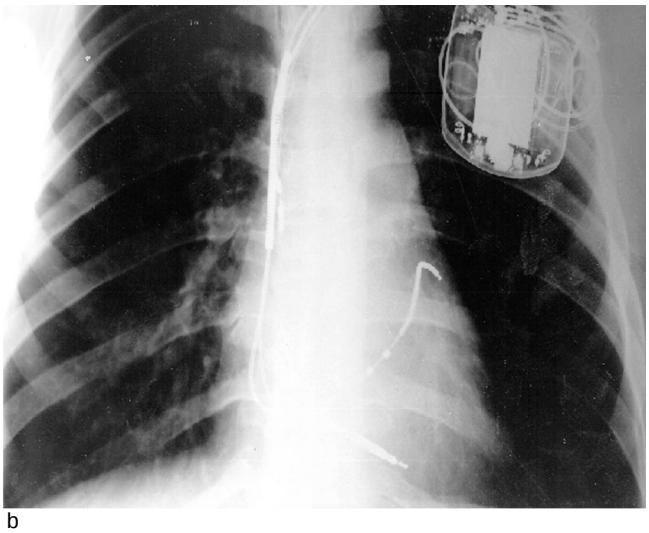
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Figure 2. A set of endocardial ICD electrodes (a) and X-ray image of an implanted Phylax AV ICD (b) (products of Biotronik, Germany).

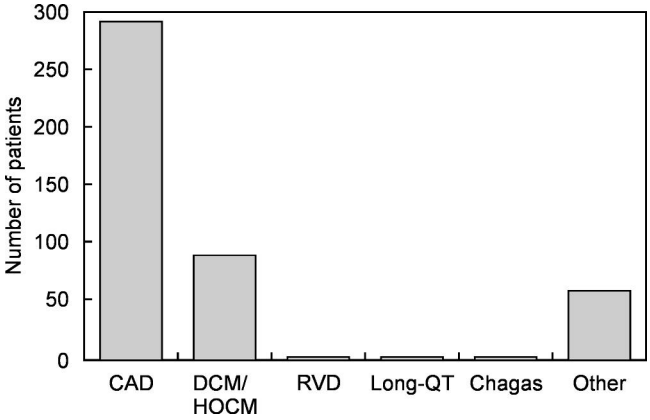


Figure 3. Primary cardiac disease in patients implanted with Phylax AV. CAD = coronary artery disease; DCM = dilatative cardiomyopathy; HOCM = hyperthropic obstructive cardiomyopathy; RVD = right ventricular dysplasia.

supposed advantages of dual-chamber ICDs were the possibility of:

- Discrimination between SVT and VT,
- Physiological pacing in the DDD or DDDR mode,
- Prevention of AF through atrial and/or biatrial pacing,
- Termination of the re-entry SVT and Afl through antitachycardia atrial pacing,
- Cardioversion and defibrillation of Afl/AF and/or VT/VF, and
- Elimination of the pro-arrhythmic risks associated with the atrial ICD application.

The first dual-chamber ICD was implanted in the mid 90s, which was followed by several thousands of successful implantations worldwide. The first subpectoral positioning of a dual-chamber ICD (Phylax AV, Biotronik, Germany) was accomplished in our clinic (Bakoulev Research Center) on April 29, 1996. The 4th and 5th generation dual-chamber ICDs have been almost exclusively used in our institution ever since, and in nearly 100 % of cases the devices were implanted in the left subpectoral region. In addition to ventricular cardioversion/defibrillation, these ICDs offer DDD(R) pacing and improved discrimination between SVT and VT. Physiological dual-chamber or atrial pacing is of major importance in patients with bradyarrhythmia and/or low left ventricular ejection fraction (EF). In patients with NYHA functional class III, appropriate atrioventricular (AV) timing may increase cardiac output by > 25 %, and left ventricular pacing can bring additional hemodynamic benefits.

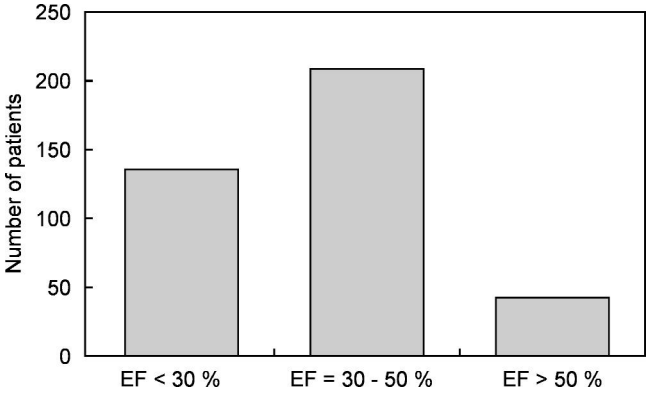


Figure 4. Available data on the ejection fraction (EF) in Phylax AV patients. The mean EF was 34.3 % ± 14.4 %.

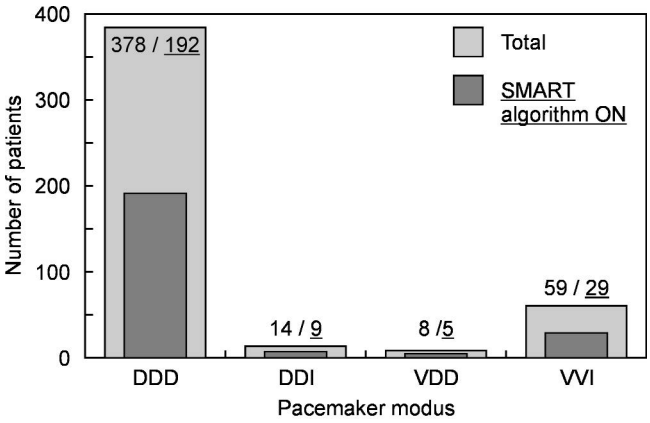


Figure 5. Distribution of selected pacing modes in Phylax AV patients. In 56 % of patients the SMART algorithm for discrimination between supraventriclar and ventricular arrhythmia was activated.

Implantation number	473
Gender	396 m (85 %), 71 f (15 %)
Mean age (years)	62.1 ± 12.1, range 10 - 92
CAD (%)	70.6
NYHA I (patients)	56
II	163
III	71
IV	10
DDD Indication (%)	82
SMART ON (%)	56

Table 1. Clinical characteristics of study patients. CAD = coronary artery disease; SMART ON = percent of study population with the SMART algorithm activated. Data on the NYHA functional class were available in 300 (63 %) of the patients.

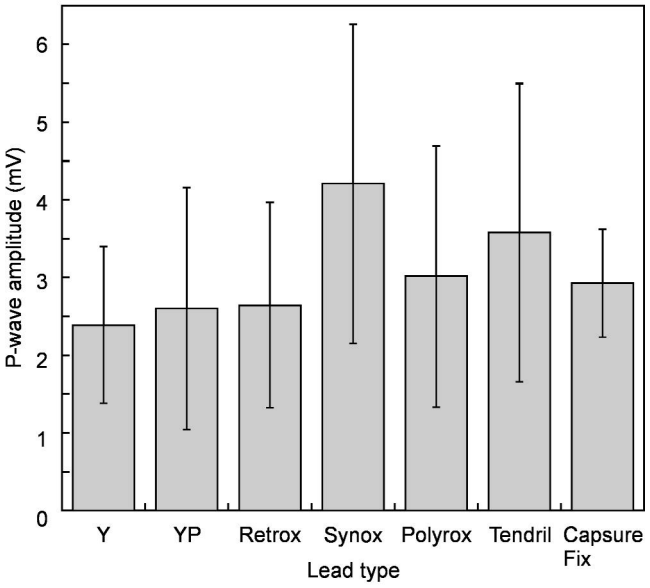
Defibrillation treshold (J)	10.6, range 5 - 28
Pacing threshold (V)	0.87 (A), 0.68 (V)
Slew rate (V/s)	0.48 (A), 1.43 (V)
Signal amplitude (mV)	2.71 (A), 15.6 (V)
Pacing impedance (Ω)	505 (A), 618 (V)
Shock impedance (Ω)	51.8
Implantation time (min)	128, range 30 - 480

Table 2. Mean values of electrophysiological parameters measured during implantation. A = atrial; V = ventricular.

Materials and Methods

The Phylax AV was the first dual-chamber ICD in the world to be implanted in the subpectoral position. The 69-cm^3 device weighing 109 g is used mostly with the active housing and several pacing/sensing and shock electrodes (Figure 2). According to the NASPE/BPEG Defibrillator code (NBD code), it relates to the DDE-DDD type, offering atrial and ventricular defibrillation/cardioversion as well as physiological DDD pacing. Data on 473 implants summarized for the period until March 2000 are presented in Table 1. The mean age of the patients was 62.1 ± 12.1 years; 70.6 % had ischemia and 27 % were in NYHA class III or IV. Dual-chamber pacing was indicated in the majority of patients (82 %). Cardiomyopathy was present in even 109 cases (Figure 3). The mean EF was 34.3 % ± 14.4 %, ranging from 30 % to 50 % in about 50 % of the patients and being lower than 30 % in 30 % (Figure 4). A peculiarity of this study population was that the majority of patients with life-threatening ventricular arrhythmia required dual-chamber pacing, contrasting other trend studies with the recipients of GEM DR (Medtronic, USA), Ventak AV (CPI-Guidant, USA), Defender 9001 (Ela Medical, France), or other ICDs.

No significant correlation was found between the pacing mode and the use of the SMART algorithm for SVT/VT discrimination (Biotronik, Germany) (Figure 5). Active fixation leads: Y (n = 164), YP (n = 68), and Retrox (n = 55) (all Biotronik) were predominantly used for atrial sensing and pacing. Nonetheless, the insertion of 79 passive fixation leads in the right atrial



Lead	Y	YP	Retrox	Synox	Polyrox	Tendril	Capsure Fix
Number	155	58	43	8	63	23	48

Figure 6. Mean ± standard deviation of P-wave amplitudes in Phylax AV patients in relation with the lead model: Y, YP, Retrox, Synox and Polyrox (Biotronik, Germany), Tendril (St. Jude, USA), and Capsure Fix (Medtronic, USA). The number of leads in which the data were available is given at the bottom.

appendage, models Polyrox (n = 67), Synox (n = 8), TIR/TIJ (n = 4) (all Biotronik, Germany), was not associated with any complication even in conjunction with the shock application within the atrium. Passive J-shaped atrial leads even exhibited significantly larger P-wave amplitudes (Figure 6). Ventricular leads with two shock coils were implanted in 209 patients and ventricular leads with one shock coil in 249. The two-shock-coil ventricular lead exhibited a lower defibrillation threshold (DFT) and permitted atrial cardioversion. Table 2 summarizes electrophysiological parameters measured during implantation. Thanks to a novel anesthesia technique that renders intubation and artificial lung ventilation redundant, the implantation time was reduced from 120 to 60-80 minutes, including electrophysiologic measurements.

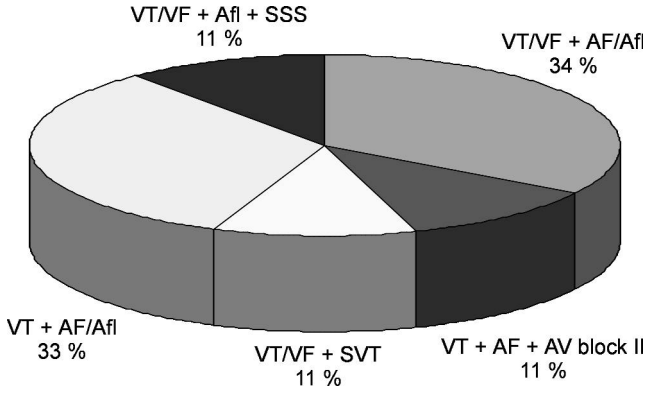


Figure 7. The arrhythmic profile of 22 patients implanted with Phylax AV at the Bakoulev Research Centre. VT/VF = ventricular tachycardia/fibrillation; Afl/AF = atrial flutter/fibrillation; SSS = sick sinus syndrome; SVT = supraventricular tachycardia.

At our clinic, Phylax AV was implanted in 22 patients in the period from April 1996 to January 2000 (for indications, see Figure 7). The first implantation of the next generation ICD Tachos DR-MSA (Multi-Site Atrial) took place on January 24, 2000 [9]. A biventricular version of the device, Tachos DR-MSV (Multi-Site Ventricular), was implanted for the first time on July 3, 2000, in combination with a coronary sinus lead for left ventricular pacing. The recipient was a 46-year-old male patient presented with ischemic heart disease, EF = 29 %, and QRS complex duration > 140 ms.

In total, 25 patients (21 male and 4 female, mean age 56.6 ± 8.2 years, range 17 – 68) received a dual-chamber ICD at our clinic and were followed for 2 to 50 months (mean 28 months) after implantation. From the 22 patients implanted with Phylax AV, 12 received a passive fixation and ten an active fixation atrial lead. The SL-ICD lead with atrial and ventricular shock coils was used in 12 patients and the SPS lead (all Biotronik, Germany) with one distal shock coil was implanted in the remaining patients. In all patients, atrial and ventricular signal amplitudes were measured during sinus rhythm and following SVT and VT induction. The atrial DFT during stable Afl/AF (with the defibrillating lead placed in the coronary sinus) and the ventricular DFT were measured in the standard fashion. In the ventricular DFT measurement, the housing of the Phylax AV served as an active electrode (anode or cathode).

Phylax AV offers DDD pacing with automatic mode switching and 8-minunte Holter monitoring of atrial and ventricular IEGMs. Under nominal settings, the ICD service life is 4 to 5 years, depending on the pacing mode. The SMART algorithm is used for SVT/VT discrimination based on the analysis of the P-P, R-R and P-R intervals and their ratios (Figure 8) [1,13]. In

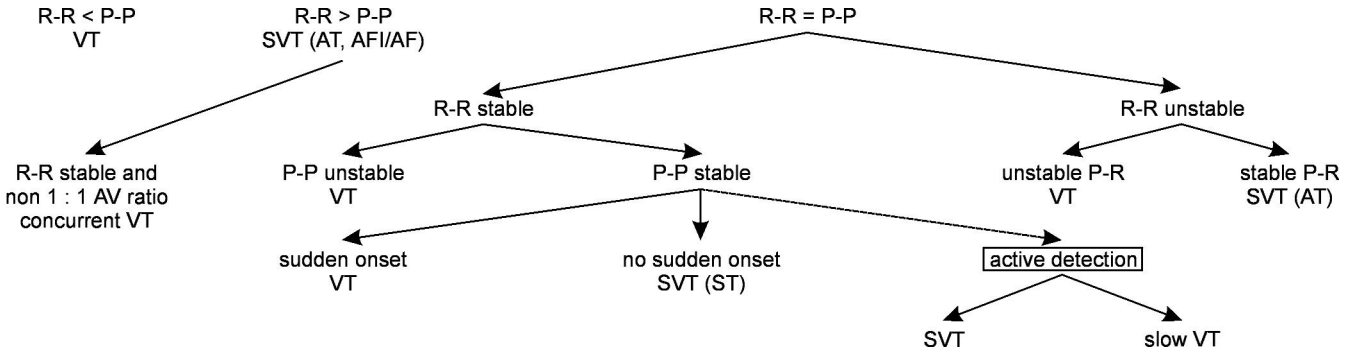


Figure 8. The SMART algorithm for discrimination between SVT and VT. SVT = supraventricular tachycardia; VT/AT = ventricular/atrial tachycardia; Afl/AF = atrial flutter/fibrillation; ST = sinus tachycardia; R-R = sensed R-R interval; P-P = sensed P-P interval; P-R = sensed P-R interval.

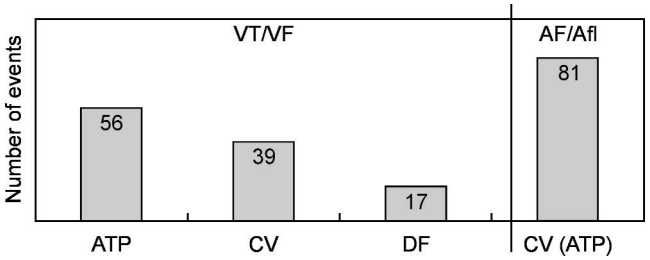


Figure 9. A review of delivered ICD therapies in 22 Phylax AV patients from the Bakoulev Research Centre, during a mean follow-up period of 28 months. VT/VF = ventricular tachycardia/fibrillation, Afl/AF = atrial flutter/fibrillation, ATP = anti tachycardia pacing, CV = low energy cardioversion synchronous to the QRS complex, DF = high energy defibrillation.

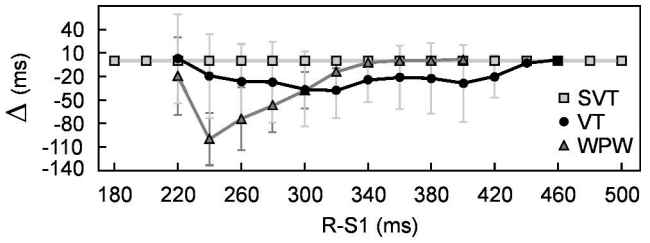


Figure 10. Clinical findings with the active SMART-II algorithm in patients implanted with the second generation Phylax AV ICDs. D interval = (A1 to A2) – (A1 to A1) in relation to the interval between R-wave and the first stimulus (R to S1) in patients with supraventricular tachycardia (SVT), ventricular tachycardia (VT), and Wolff-Parkinson-White syndrome (WPW). Changes in the D interval in SVT and WPW significantly differed from that in VT ($P < 0.002$ and $P < 0.0001$, respectively).

brief, if the atrial rate exceeds the ventricular rate and the duration of the R-R interval is not within the VF zone, the arrhythmia is considered to be an SVT. Sensitivity and specificity of the algorithm have been tested under clinic settings as well as using 23 arrhythmia episodes stored in the database of the Ann Arbor Medical Center (University of Michigen, USA). The Phylax AV offers all kinds of automatic treatments for VT/VF as well as manually activated therapies for Afl/AF and SVT.

Results

During 2 – 50 month follow-up of the 22 Phylax AV patients in our institution, 112 therapies were delivered on SVT and VT/VF (Figure 9). In 81 cases, endocardial atrial defibrillation was activated manually to terminate Afl/AF. Additional 13 patients required dual-chamber pacing due to bradyarrhythmia or AV conduction disturbances. Overall, 80 % of the patients benefited from the dual-chamber version of the ICD. To prevent frequent VT attacks during the postoperative period, cordarone was prescribed to the majority of patients (250 – 300 mg/day).

Test results and Holter IEGM analysis in Phylax AV patients have demonstrated that the SMART algorithm exhibits 100 % specificity in the discrimination between Afl/AF and VT (in-clinic settings). Utilization of coronary sinus leads reduced atrial DFT from 4.6 ± 2.8 J to 2.2 ± 0.3 J ($P < 0.025$). Afl/AF was either induced or occurred spontaneously during the implantation procedure, with the DFT determined up to 5 minutes after the onset of Afl/AF. A mean left

atrial diameter in our patient group was 4.5 ± 0.4 cm. Despite the high specificity of the SMART algorithm in the discrimination between Afl/AF and VT, the algorithm was non-specific for SVT detection – the same therapy would be delivered on SVT with 1:1 AV conduction as during VT. Therefore, the SMART-II algorithm for active SVT/VT discrimination has been developed at our institution. In the SMART-II algorithm, an extra stimulus is applied in the ventricle during slow VT with 1:1 AV conduction. The A1-A1 and A1-A2 intervals are measured prior to and during the extrastimulus delivery.

According to Figure 10, SVT (excluding the Wolff-Parkinson-White syndrome) was associated with no change in Δ interval = (A1 to A2) – (A1 to A1). In VT, Δ interval changed by > 20 ms. It is very important to deliver the ventricular extrastimulus at a 50 – 100 ms shorter interval than VT cycle length (during the His bundle retrograde refractory period) as pro-arrhythmic effect is possible with a longer interval, especially during SVT or sinus tachycardia. The SMART-II algorithm with the option for discrimination between arrhythmias with 1:1 AV ratio eliminates the only perceived limitation of the original SMART algorithm. No complication has been observed in patients implanted with Phylax AV. The second generation of Phylax AV ICDs (incorporating the SMART-II algorithm) has been evaluated in 6 patients. The device was implanted in the combination with a helix-shaped lead with the shock coil and two ring electrodes placed in the coronary sinus, which allows for biatrial pacing and atrial defibrillation. Atrial DFT has been significantly reduced from 4.6 ± 2.8 J (for shocks between the right atrium and right ventricle/active housing) to 1.2 ± 0.3 J (for shocks between the right atrium and coronary sinus/active housing). The mean implantation time of the three leads, i.e. coronary sinus lead, the right ventricular lead (SL-ICD), and the right atrial lead (Synox or Y lead), with electrophysiological testing was 120 ± 35 min.

While bringing decision to implant an ICD, we had in mind that other anti-arrhythmic therapies (medications, ablation, or surgery) were either insufficient or contraindicated. Up to date, there are no absolute indications for dual-chamber ICD implantation. It must be noted that electrotherapy only terminates arrhythmia, whereas catheter ablation or surgery may eliminate it. The following analysis of worldwide ICD implantations will help in the outlining of the main trends in the development in this field.

Discussion

Description of Other ICDs

Each of the ICD models listed in Table 3 incorporates an original SVT/VT discrimination algorithm. In 1995, the Defender 9001 (Ela Medical, France) became the first clinically approved ICD for abdominal implantation. The SVT/VT discrimination or differentiation implemented in this ICD is based on the PARAD algorithm, which includes analysis of atrial and ventricular rates, R-R interval stability, AV association, and identification of the chamber (atrium or ventricle) that is the first to increase the rate at the tachycardia origin [8]. The latter option plays the primary role in discrimination between SVT and VT episodes with 1:1 retrograde ventriculoatrial conduction. The drawback of the

	SVT/VT discrimination algorithm	DDD pacing option	Treatment of atrial tachyarrhythmia
Defender 9001 (Ela Medical, France)	+	+	-
Phylax AV (Biotronik, Germany)	+	+	+
Ventak AV (CPI-Guidant, USA)	+	+	-
Res-Q Micron (Intermedics, USA)	+	-	-
Jewel II Micro (Medtronic, USA)	+	-	-
Jewel AF, 7250 (Medtronic, USA)	+	+	+
GEM DR (Medtronic, USA)	+	+	+

Table 3. Diagnostic and therapeutic options in dual-chamber ICDs. SVT = supraventricular tachycardia; VT = ventricular tachycardia.

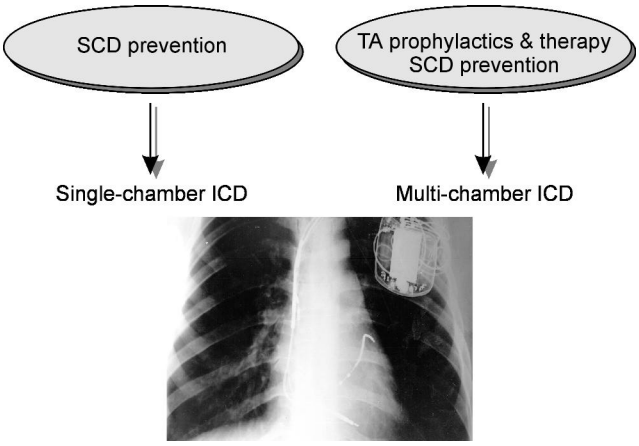


Figure 11. Modern approach to tachyarrhythmia (TA) prevention and treatment with electrotherapy. SCD = sudden cardiac death.

Defender 9001 system is the necessity of abdominal implantation and a lack of the atrial tachycardia therapy option. It should be emphasized that PARAD I-II algorithms provide 93 % specificity to prevent inappropriate shocks during AF. The device has demonstrated 100 % sensitivity in VT/VF detection.

Ruppel et al. [10] and Oswald et al. [11] have gained the largest clinical experience with the dual-chamber Ventak AV (CPI/Guidant, USA) ICD implantation. First of all, they used atrial and ventricular rate characteristics and demonstrated SVT and VT discrimination with 91 % specificity, with the VT/VF electrotherapy sensitivity being 100 %. However, Afl/AF detection and therapy are not available in this system.

RES-Q Micron ICD (Intermedics, USA) can hardly be compared to the 5th generation device; while it provides optimal VT detection and therapy characteristics, the device has a two-channel IEGM Holter, allowing electrotherapy analysis only retrospectively, i.e., just as in a single-chamber ICD.

In January 1997, Luderitz successfully implanted the Jewel 7250 dual-chamber ICD (Medtronic, USA) offering an automatic SVT therapy option. The Jewel II Micro and Jewel 7250 ICD families are equipped with different discrimination algorithms, including morphology analysis of the ventricular signal (its duration) that is registered at the endocardial shock electrode with the ICD housing as the reference. The discrimination specificity is not higher than 80 %, and the information is rather poor, especially in patients with His bundle block. Another algorithm is used in Jewel VF 7250 and GEM DR that includes analysis of P- and R-wave time intervals for determination of atrial and ventricular rates. A rate parameter (P-P interval) is used to discriminate SVT from Afl/AF. The algorithm was tested at Mayo clinic [12]. Results demonstrated that inappropriate shocks at Afl/AF could be reduced by 72 %. The sensitivity at VT therapy was the lowest in comparison with other tested systems (98 %), while sensitivity at SVT detection with 1:1 AV conduction was very high (98 %) (Table 4).

Comparison of Single- and Dual-Chamber ICDs

Extensive clinical experience shows that single-chamber ICDs with active housing may be implanted transvenously in 99 % of patients, with the mean DFT £ 10 J. New lead designs, fractal electrode coating, bi-phasic defibrillating shock waveforms, and a reduced physical size of ICDs allowed for subpectoral ICD implantation to be performed within one hour. This represents a clear improvement in comparison to lengthy and intricate abdominal or transthoracic ICD implantation. According to our own experience and related literature, a large portion of the ICD patient population (20 % – 40 %) requires dual-chamber ICD treatment [1,2,6, 11,13,14]. We deem that in patients with normal left ventricular function, termination of AF with 2-3 J

	SVT sensitivity	VT/VF specificity
Defender 9001, 9201 (Ela Medical, France)	93 %	100 %
Phylax AV (Biotronik, Germany)	95 %	100 %
Ventak AV (CPI-Guidant, USA)	89 %	100 %
Jewel II, 7218, 7223 (Medtronic, USA)	88 - 96 %	76 % VT, 100 % VF
Jewel AF, 7250, GEM DR (Medtronic, USA)	92 %	99 %

Table 4. Sensitivity and specificity of SVT/VT discrimination algorithms. SVT = supraventricular tachycardia; VT/VF = ventricular tachycardia/fibrillation.

shocks is possible in the manual atrial defibrillation mode without pro-arrhythmic effects (ventricular arrhythmia induction).

The future development of dual-chamber ICDs offering DDD(R), biatrial and biventricular pacing may be regarded as a task with social and economic priority, potentially solving the problem of automatic anti-arrhythmic electrotherapy (Figure 11). Application of coronary sinus leads (or a patch electrode attached onto the left atrial epicardial wall via mini-invasive

floating leads, is expected to further reduce atrial DFT as well as the number of implanted endocardial leads. Although many of these schemes are still in the domain of theory and experimental research, there is a promise that an automatic device for resuscitation of the patient in the event of a blood-circulation collapse may be developed (this idea was first outlined by Y. Bouvarin and F. Zacouto and considered insolvable in 1961). Significant expansion of ICD capabilities and improved device efficacy in the prevention of sudden arrhythmic death do not diminish the role of the physician, whose prerogative is to decide which method should be used to eliminate arrhythmia. Multi-component "hybrid" therapies are possible, comprising various pacing methods, catheter ablation, tachyarrhythmia surgery, and/or dual-chamber ICD implantation.

Clinical experience with Phylax AV and other dual-chamber ICDs suggests that the incidence of inappropriate therapy decreases from 15 % – 40 % in single-chamber devices to 2 % – 3 % in dual-chamber units. The problem of SVT/VT discrimination under conditions of 1:1 AV conduction remains to be solved, and new algorithms capable of analyzing the R-wave and P-wave morphology are under development. Such algorithms, however, significantly increase ICD battery energy consumption, reducing the lifetime of the device.

The main advantage of dual-chamber ICDs over single-chamber units is the opportunity for DDD(R) pacing. This feature was valuable in 82 % of the 473 patients implanted with Phylax AV in 13 European countries. The problems such as far field R-wave sensing in the atrial channel and the algorithm sensitivity < 100 % remain to be solved. Prevention of SVT, Afl/AF, and VT is currently among the major research topics in the field of cardiac pacing and electrophysiology. A universal electrotherapy of refractory tachyarrhythmia is of primary importance despite the availability of highly reliable prophylactic devices.

Conclusion

Two main trends in the development of ICDs are:

- prophylactic implantation of so-called "simple" devices, and
- implantation of complex programmable multi-chamber ICDs for prophylactic and pacing therapy of a wide spectrum of tachyarrhythmia.

The modern technology provides the foundation for a universal tiered-therapy device offering:

- prevention of tachyarrhythmia induction by dual-chamber and multi-site pacing,
- reduction of the discomfort caused by inappropriate shocks by sensitive and specific AV-discrimination of the arrhythmia locus,
- new ways to improve hemodynamics by multi-site (biatrial and biventricular) pacing, and
- improved patients' quality of life.

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